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Mobilising the experiential knowledge of clinicians, patients and carers for applied health-care research

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This article demonstrates the benefits of combining various types of knowledge for applied health research. Funding is available for health research despite these being 'austere times' for public services and international policy shifts recognise the role that patients, carers and the public can play in research. In England the National Institute for Health Research, Research Design Service (RDS) was created to ensure that the experiential knowledge of clinicians working in the National Health Service is informed by methodological expertise to achieve relevant research outcomes. The RDS also facilitates patient and public involvement in research, framed as 'PPI'. This raises the question of how PPI impacts on research design and funding and which patients or members of the public should be involved in which aspects of research. To answer these questions we present case studies that draw on the expertise of academics, clinicians, patients and the public in applied health research. These cases demonstrate that where patients with direct experience of the condition that is to be studied are actively involved as advisers early on in applied health research, this can enhance the likelihood of successful funding applications, ethical aspects of research and the relevance of questionnaires and interventions to patients. For comparative purposes, we give an example of an unsuccessful research proposal. We contribute to theoretical development through refining the conceptualisation of PPI by unpicking the different roles that members of the public play as lay people, distinguishing this from the specific expertise that comes from direct experience of being a service user, carer or patient. We conclude that different types of knowledge are required for applied health research: methodological expertise, practice-based expertise, and the experiential expertise of patients or carers. While there are no guarantees, the scrutiny function performed by lay involvement in research funding panels can challenge the balance of power.

Keywords: patient and public involvement; impact; research design; knowledge mobilisation; lay expertise

Introduction

In this article we set out the policy context for patient, carer and public involvement in applied health research before outlining some challenges that arise in translating such policy into action. There is a known gap in reporting as published studies rarely focus in depth on involvement processes, especially when these are challenging and result in less-than-positive outcomes (Brett et al., 2012). We present three case studies derived from our experience of working as

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researchers across the boundaries of clinical knowledge, academic research, the discipline of social science and the experiential knowledge of patients and carers. Our aim is to demonstrate how effective mobilisation of a range of relevant sources of expertise impact on research design and funding. In comparing these cases we answer the question of how PPI (a commonly used acronym denoting patient and public involvement in research) can impact on research design and on funding as well as the question of which patients or members of the public should be involved in which aspects of research. We discuss the implications of the cases before concluding that the term 'PPI' requires further conceptual unpicking and that collaboration between academics, clinicians and patients and the public is neither a 'quick fix' nor a cheap solution but requires time, money, facilitative skills and an appreciation for expertise that is derived from direct experience.

Prior to policy developments around 'expert patients' where patients are regarded as co-producers of health, there has been a tendency to privilege clinical expertise over subjective knowledge (Wilson, Kendall, & Brooks, 2007). Historically, people have been involved in medical research primarily as the passive subjects of research; they may agree to be experimented on in clinical trials or studied as sources of data to suit the pre-defined purposes of researchers. In sharp contrast, the rationale for actively involving patients, carers and members of the public in research has been characterised as inherently democratic – worthwhile in and of itself, based on assumptions that citizens are entitled to participate in research that affects their own lives or those of others and recognising that much research is funded through public money. Besides a normative, democratic rationale, policy statements also refer to an instrumental rationale – i.e. that involvement of the public in research is worthwhile because the ends (posited as more relevant and more ethical research) justify the means, i.e. PPI (Koops & Lindley, 2002). One recent article that put forward recommendations for good practice in PPI explicitly stated that the researchers sought to involve patients for 'pragmatic' rather than 'ideological' considerations (Wright, Foster, Amir, Elliott, & Wilson, 2010) but debates about values in relation to 'science' persist (Gibson, Britten, & Lynch 2012). Lay people who get actively involved in research may be described as 'consumers' or 'service users' and there are acknowledged tensions associated with different definitions within the emergent field of PPI (McLaughlin, 2009). In this article we adopt the commonly used acronym 'PPI' using INVOLVE's definition of patient and public involvement in research, (INVOLVE, 2012) where people are involved not as *subjects* but as active *partners* in research (Barnes & Cotterell, 2011; Morrow, Boaz, Brearley, & Ross, 2012). This knowledge mobilisation and value placed on the experiential or lay knowledge of patients, carers and the public represents a challenge to traditional ways of scientific understanding whereby experts know best and lay people may be regarded as biased in their views (Beresford, 2005).

Policy context

Despite this being a time of financial austerity that is impacting on public service budgets, there are economic drivers for a knowledge economy and efficient health services (Department of Health, 2006). In England the National Institute for Health Research (NIHR) provides a range of funding streams spanning the 'research innovation pathway' from research characterised as 'invention' through 'evaluation' and 'adoption' to 'diffusion'. Applied health research has been termed 'mode 2 research', concerned not with knowledge generation per se but with what is known in health policy terms as 'bench to bedside' or translational knowledge, intended to directly inform health service practice (Department of Health, 2006; Ferlie & Wood, 2003). This relates to broader debates outlined in the article by Bannister and O'Sullivan in this special issue (2013). Whereas mode 1 research or basic science, sometimes termed 'blue skies

research' focuses on exploration and scientific discovery, often driven by intellectual curiosity within specific disciplines, applied health research may be inter- or trans-disciplinary, intended to lead to improvements for patients and/or health systems within a relatively short timescale. In order to gain funding for applied health research, applicants are therefore required to translate across and between patients' subjective individual experiences, practically oriented, clinical knowledge as well as being methodologically rigorous. Securing funding for applied health research is a highly competitive process, involving peer review and often lay review of proposals. Members of the public may also be involved as lay members of funding panels, contributing to the decision-making process (O'Donnell & Entwistle, 2004).

There is international policy support for PPI. Initiatives include the Cochrane Consumers Network, the Consumers' Health Forum of Australia https://www.chf.org.au/history.php, the Canadian Institutes of Health Research Citizen Engagement Framework, The Health Council of the Netherlands (Elberse et al., 2012) and in the US members of the public are involved in the Director's Council of Public Representatives (COPR, see http://copr.nih.gov/). The NIHR has invested in the advisory body INVOLVE and 2008 saw the creation of 10 regional Research Design Services (RDSs) which support researchers seeking NIHR funding (INVOLVE, 2009). These RDSs provide PPI advice and guidance, as well as specialist methodological advice and guidance such as qualitative methods, statistics and health economics. Researchers applying for funding to conduct research are increasingly expected to provide a statement of how they have involved patients, carers and members of the public in their research designs and how they plan to involve them throughout the course of the research after funding has been awarded. Here, we report on our experience (from within an RDS service and the Arthritis Research UK Primary Care Centre) of mobilising these distinct forms of expertise – academic, clinical and the experiential knowledge of patients.

PPI in practice

PPI is rarely studied as a phenomenon; hence, our focus here is on process as well as impact. More usually, published studies briefly acknowledge PPI as contributing to research processes but, partly due to word count constraints and academic journal requirements, often there is limited discussion of PPI processes and outcomes (Staniszewska, Brett, & Mockford, 2011). It can be difficult to locate evidence on the effectiveness of PPI; although a systematic review (Staley, 2009) found that PPI was reported to:

- Increase recruitment to all types of research
- be of particular value in *qualitative* research where participants are asked to share their views and experiences
- be of particular value in *clinical trials* where it helped to improve trial design and ensured the use of relevant *outcome measures*
- benefit the people involved as well as the research participants (Staley, 2009, emphasis in the original).

Staley's review noted in particular the lack of evidence on the impact of public involvement on research funding and here our article makes a key contribution. Drawing on findings from three reviews of PPI, INVOLVE argues that public involvement can help to make a study more ethical (INVOLVE, 2012). A review of 'public involvement' in the design and conduct of clinical trials identified nine papers (Boote, Baird, & Sutton, 2011) but despite identifying specific characteristics of people who were involved such as HIV-positive mothers, stroke survivors and aboriginal health workers, the review authors conflate these using the term 'the public' which leads us to the

question raised by Williamson (2007) 'how do we find the right patients to consult?' Boote et al. note the tensions between the usually large numbers of trial participants and usually smaller numbers who can be actively involved. These tensions between involving a large number of people in consultation exercises versus collaborating more intensively with smaller groups have also been noted by Burton (2009) and Tritter and McCallum (2006). What Burton terms the 'extreme case formulation' of involving *everyone* prompts the thorny issue of 'representativeness' and in this article issues of representation, consultation and involvement are crucial, especially in the third case study that we present. The need for funding to facilitate PPI is also identified in the review by Boote et al. (2011) and in our second case study we show how a small amount of funding in the form of a PPI bursary can facilitate involvement.

Translating PPI policy into practice is also not a simple or straightforward process (Ward et al., 2010). Some organisations active in health research have established consumer panels or 'research user groups' to facilitate PPI (Howe, Delaney, Romero, Tinsley, & Vicary, 2010; Wyatt et al., 2008) and the James Lind Alliance was formed to bring together clinicians and patients to establish priority setting partnerships (Stewart & Oliver, 2008). Other researchers have worked with patients and/or service users in a more emancipatory 'bottom-up' mode. Although there is a history of user-led research (Barnes & Cotterell, 2011) this form of knowledge mobilisation can encounter resistance from researchers suspicious of the 'usual suspects' (Wright et al., 2010) unwilling to cede control (Glasby & Beresford, 2006) agnostic or sceptical about involvement (Becker, Sempik, & Bryman, 2010) or hostile to 'unrepresentative' views (Little et al., 2002). There are also practical financial barriers to involving patients, carers and members of the public early on in research design as funding for this process may be difficult to find in advance of a funding award (Staniszewska, Jones, Marshall, & Newburn, 2007). Of course patients and the public are not a homogenous entity. Some authors have made use of Nancy Fraser's work on weak publics or counter-public(s) (Gibson, Britten, & Lynch, 2012). Frequently the undifferentiated collective noun 'the public' is conflated with specific sub-sets of public(s), namely patients who have experience of a particular medical condition. Others have analysed the various issues associated with different consumer groups. For example, Baggott, Allsop, & Jones (2005) note that patients with chronic conditions such as arthritis generally engage in co-operative relationships with health professionals, whereas there have been alliances but also tensions between pregnancy and childbirth health consumer groups, midwives, gynaecologists and obstetricians. Historically mental health user groups have campaigned against coercive practices and Peter Beresford is a well-known service user/academic advocate of user involvement (Glasby & Beresford, 2006). The involvement of people with neurodegenerative diseases in research is discussed by Iliffe, McGrath, and Mitchell (2011).

Patients, carers and members of the public have different motivations for becoming actively involved in research. These include altruism, the opportunity for personal development and a desire to influence change (Tarpey, 2006). Recognised principles of good PPI practice include researchers taking responsibility for providing feedback and acknowledgement and developing on-going dialogue through relationships, rather than adopting 'hit and run' tokenistic practices or 'tick box' managerialist approaches (McLaughlin, 2010). These dialogic processes have been analysed using variants of Habermas's theory of deliberative democracy (Evans & Kotchetkova, 2009) but dialogic practices have also been found wanting. For example in a report on an empirical study of the National Institute for Health and Clinical Excellence (NICE) Citizens Council (Davies, Wetherell, & Barnett, 2006) the authors cogently point out that '. . . the ordinary public . . . have in the most part not read Jurgen Habermas or Iris Young' (p. 148). Their findings demonstrate potential contradictions between open dialogue and setting ground rules for inclusive practice. Some citizens had disagreed on issues of equality and diversity and resisted a session concerning ground rules for dealing with prejudice as 'political correctness'. The ethnographic study by Davies et al. aimed to

inject a dose of realism into theoretical debates about public participation and in a similar pragmatic vein, there are empirical examples of how research-active organisations (Howe et al., 2010; Wyatt et al., 2008) and some RDS services have facilitated PPI through investment in support staff and an organisational infrastructure for PPI (INVOLVE, 2009). The nature of this support may include training, provision of a glossary of terms to aid communication, agreed statements of roles and responsibilities and financial reimbursement direct to patients and the public to enable involvement. Debates in the more sociologically oriented literature focus on the risk of 'institutional capture' (Kerr, Cunningham-Burley, & Tutton, 2007) whilst others maintain that it is possible for service users who get involved in research to 'stay native' (Gillard, Turner, & Lovell, 2010). In the next section we demonstrate how in two cases PPI led to positive impacts. Our third case illustrates how academic and clinical knowledge was presumed necessary and important but the experiential knowledge of patients was undervalued with negative consequences.

Empirical examples of involvement in applied health research design

Case study 1: PPI in developing foot pain research

Case study one illustrates the value of inviting people with experience of a chronic condition to critically appraise research instruments and processes. A Research User Group was established by the Arthritis Research UK Primary Care Centre in 2006 to facilitate the active involvement in research of people with lived experience of a range of musculoskeletal conditions. The group is supported by an organisational infrastructure including a PPI Co-ordinator and a User Support worker. Members of the group are involved in advising researchers on many aspects of the research cycle and are regularly consulted for their views on funding applications and have been involved in a range of studies including clinical trials, cohort studies and qualitative research.

Foot and/or ankle pain is a common problem in the population with approximately one in five people of middle to older age affected (Thomas et al., 2011). The impact of foot pain and problems can be considerable, contributing to reduced mobility (Peat, Thomas, Wilkie, & Croft, 2006), difficulties with balance and increased risk of falling (Menz, Morris, & Lord, 2005, 2006; Tinetti, Speechley, & Ginter, 1988). In designing a prospective population-based observational cohort study to describe the prevalence of foot osteoarthritis (OA) and describe the natural history of foot OA (Roddy et al., 2011), researchers sought advice from people with foot pain in two phases; first when designing a self-completion questionnaire and second when testing a clinical assessment of the foot.

The questionnaire was designed to be posted to approximately 9000 patients to generate knowledge about how people experience foot pain. Therefore, it was vital to ensure that the questions made sense to patients and that they found it easy to complete. In phase one, researchers (DC, MT and CJ) collaborated with patients to review a new self-completion questionnaire on foot pain in adults 50 years and over. The questionnaire had been designed by a team of clinicians and researchers based upon past research experience and included both previously validated outcome measures (e.g. Short Form-36; Ware & Sherbourne, 1992) and new foot-pain-related elements. Drawing on techniques of cognitive interviewing (Campanelli, 1997; Tourangeau, 1984; Willis, 1999) researchers asked patients to 'think out loud' in order to examine four potential sources of response error. These included how respondents understand questions (comprehension), recalled memories (recall), made decisions (judgment/decision-making) and constructed their answers (response) (Willis, 1999). Five members of the Arthritis Research UK Primary Care Centre's Research Users' group were invited to participate in the cognitive interviews, which were audio recorded and transcribed verbatim.

The respondent-led technique requires people to talk about their thoughts while they think in response to a question (Willis, 1999). Probes were used by the researchers to elicit in-depth understanding of question completion (e.g. what does this term mean to you? how easy or difficult did you find answering the question? Can you repeat the question in your own words?) The researchers and patients went through the questionnaire page by page. Difficulties emerged with the completion of the new footwear section. On occasions, people were unsure whether specific questions related to them. For example, 'Oh I wondered whether these were ladies and those were men's' and 'I didn't realise you wanted me to fill in all the age groups, I thought it was just my age group now'. The ability to completely explain some questions was also discussed, 'but you can't can you? You can't have comprehensive pictures of all shoes, you've not got wedges'. After reviewing the whole questionnaire patients gave feedback on missing dimensions and felt the problem of fatigue had not been addressed. In summary, in response to patient views changes were made to the layout of and instructions to questions in the footwear section and a new question on tiredness was added to the questionnaire.

The second phase of the cohort study is a clinical assessment of peoples' feet. Five patients attended the training session for clinicians who would be conducting the assessment in the main study and were examined by each of the seven assessors. Following their examinations participants were questioned separately by a researcher (MT) about key issues related to comfort and positioning, clarity of instructions, running order and any additional comments. Verbatim quotations were written down by the researcher. Issues and concerns raised by patients are displayed in Figure 1.

A feedback meeting with all the assessors was held as part of the training event. Issues highlighted by patients about use of equipment, communication and the overall experience were raised and therefore informed how physiotherapists and podiatrists subsequently delivered the assessment in the main study to ensure that study participants were treated appropriately. In summary, researchers and clinicians have benefited from the experiential knowledge of patients with foot pain when designing a prospective cohort study of foot pain in adults 50 years and over. Patients were involved in the design of a new questionnaire survey and a foot assessment for research clinics. Advice was gained on questionnaire layout, content and format, and the overall experience of a research clinic. Patient involvement made an important contribution to this particular study and there is an on-going relationship between the patients and clinical and non-clinical researchers. One patient has gone on to give presentations about their PPI experience at a national conference and a regional workshop. Their skill in public speaking has increased so that for their second presentation they found the confidence to speak to an audience that included academics and National Health Service staff (including a consultant) with the aid of brief notes.

Case study 2: co-production of useful knowledge through collaborative design

Here, data are drawn from an RDS PPI bursary monitoring report. At the time of writing the research proposal has been funded but the research is yet to start. We report on involvement in design as well as planned involvement throughout the research. An academic researcher (a psychologist with an interest in memory loss and an RDS client) involved a group of Parkinson's disease patients and carers in a funding application for a study of the impact of different medications on memory loss. The RDS advised on appropriate methodology for a randomised controlled trial besides advising on PPI and the application was successful. Prior to the active involvement of the patient group, the academic acknowledged that the focus of the study was primarily 'scientific', concerned with a robust study design measuring dependent variables.

Topic	Patient feedback	Action taken
Experience of assessment	"I started to have a bit of stiffness" "Felt like I needed to change my stance. I was stood for over ten minutes" "Back ache over 5 mins – under five mins would be better"	Assessors advised to be sensitive to how patient is feeling, be as timely as possible and to allow breaks if needed.
Communication	"Some people never said a word – it was too quiet at times" "Poor explanations. Would have liked to have been told to relax when being examined when weight-bearing" "There is lots of changing and not sure what is going on"	Assessors advised to talk to the patient during the assessment and explain what is happening and what is coming next.
Use of Equipment	"Some tools scratched when testing movement" "Ruler corners are very sharp and dig in" "Too much pressure"	Assessors advised to place equipment carefully and to think about amount of pressure used.
Hand movements/placing	"Always have one hand on the foot so not startled by touch".	Assessors advised to think about their hand movements and try to have continuous contact.

Figure 1. Issues raised by patients during training for clinical assessment of the foot.

Well in advance of the application being submitted, funding was awarded by the RDS to facilitate PPI in the research design phase and the academic researcher was directed towards INVOLVE's resources. To put patients at their ease and ensure their meaningful contribution, a meeting was arranged with refreshments at a pub, an informal venue, chosen by the group and located in the community rather than the academy. Funding was allocated to pay for refreshments, travel costs and a focus group transcriber. As in the case of the foot study, the researcher and the group of patients and carers had, over time, built up a relationship of trust but here the researcher acknowledged that they had been used to 'talking at' rather than engaging in equal dialogue *with* group members. The relaxed environment enabled patients and carers to discuss the proposed study which planned to examine the effect of different medications on memory loss. Focus group participants were provided in advance with a copy of the aims for the meeting, themes to be discussed and the lay summary of the funding bid.

The focus group was structured around the need for and perceived relevance of the research as well as the study design. The discussion was facilitated rather than directed by the researcher and their assistant. The group agreed that the topic was worthy of research as forgetfulness carries serious risks for patients and carers in their everyday lives. They enlightened the researcher about the impact of the condition, persuading the formerly quantitatively oriented researcher of the merits of including qualitative methods to gain rich and detailed insight into patients' and carers' experiences. The group discussed the proposed clinical memory tests and their relevance in relation to their experience of the disease. They also discussed drafts of patient information which are essential to recruitment procedures. As in the first case study, medical language predominates within the application for funding but the lay summary was discussed with the group and non-scientific terms used to ensure comprehension. Actively involving patients and carers led to a change in the study design so that an additional research meeting was introduced and semi-structured interviews were added. The interviews will give patients and carers a voice that they otherwise would not have had in a traditional quantitative study design, with the opportunity to describe what being a research participant feels like and to explain from a subjective perspective what effects medication have on activities of daily living. Co-interviewers, recruited from the group, will help shape the interview questions, be active in the interview itself and in the interpretation of the data that are collected. This has the potential to challenge the scientific expertise of the research team, ensuring that patient and carer perspectives are considered. In addition, group members will be involved in dissemination of the research, contributing to reports to ensure they are comprehensible to a lay audience and use appropriate means of communication and media formats, including for example local radio. In summary, knowledge in this case will be co-produced via a collaborative process, mobilising academic and clinical but also patient and carer expertise. This collaborative approach is a radical change from the original ideas of the researcher who has been willing to engage in a learning process alongside patients and carers.

Case study three: 'mobilising knowledge from feedback'

With permission from a further group of RDS clients – in this case practising clinicians – here we use a funding application form and a letter from a funder as data. A senior experienced practising clinician with an interest in diabetes devised a protocol to study women who have recently given birth in order to assess the risk of themselves and/or their babies developing complications associated with diabetes. Notably, the majority of the funding application form (as required by the funder) was expressed in the language of medical science, including terms not immediately recognisable by many lay people such as 'post-partum' and 'anthropometric'. However, the lay summary section explained in simpler terms the need to study the risk of gestational diabetes and the clinicians worked in an iterative relationship with the local RDS to address the methodological aspects of

the study, ensuring that the application was sound in scientific terms. This included, for example, the design of a pilot study to inform the calculation of a sample size that would enable statistical validity within a subsequent definitive clinical trial. The clinician had completed a PPI section of the funding application form explaining that they had recruited support from the Chair of a local diabetes group and a male 'expert patient' with diabetes. They also acknowledged ethical issues, explaining that the oral glucose tolerance test (OGTT) currently used in practice is unpleasant to taste. However, the research team anticipated that women would give consent to take part in the study and thus commit to undergoing two of these tests as well as a continuous monitoring test comprising a subcutaneous device to be fitted at least 6 weeks after childbirth and worn for 5 days. The proposal was submitted to the NIHR Research for Patient Benefit scheme.

Staff working in RDSs (which are based in academic institutions) facilitate funding bids but may not necessarily hear the outcome of applications, as the responsibility for submitting the application remains with the lead researcher. In this case, the RDS had established a positive working relationship with the clinician leading the funding bid who was willing to share data (and so share knowledge) in the form of feedback from the funding panel comprising three anonymous reviews and a letter from the Programme Manager. The application for funding was considered but rejected by the panel. As reviews are returned anonymously, we do not know whether one or more of these may have been a lay reviewer, although this particular funding programme does seek lay reviews. Reviewers commented that, despite the research team having consulted with a local diabetes group, there appeared to have been insufficient consultation with women having direct experience of the condition to be studied. One reviewer, using the first person pronoun made direct reference to their own experience of wearing an insulin pump and demonstrated insight into the perspective of people who live with diabetes, hypothesising that the researchers might find it difficult to recruit women into the study. There are known challenges with recruitment to clinical trials (Treweek et al., 2010) and this reviewer seemed to be capable of putting himself/herself in the place of women who might be recruited into the clinical trial, identifying personal and social barriers that might affect the feasibility of recruiting women as participants:

> It is worth considering the question of how well participants will tolerate the implanted sensor. The applicants are not just looking to recruit 300 women with GDM (gestational diabetes mellitus); they are looking to recruit 300 women with GDM who do not have needle phobia and who are happy to wear a subcutaneous cannula for a week with a recording device stuck to their abdomen. My experience as an insulin pump user tells me that many women will reject systems such as this on aesthetic grounds even if they know that there is a potential health benefit.

Another reviewer also recognised that study participants have busy lives outside of the trial and that participation in research can carry economic consequences:

> All women by definition will have small children and having two OGTTs in two weeks will be problematic if childcare facilities are not provided (more expense!)

The third reviewer also commented on PPI:

> The local diabetes group are involved and appear to be regularly supportive.
> This cohort of individuals have as yet not been approached and may have their own challenges – they will by definition be a young female cohort with young families and this has not been explored in the application. Whilst consultation has taken place there is no evidence that a representative of the potential study group has been involved.

The letter from the Programme Manager acknowledged that the research team was addressing an important problem but passed on comments from the funding committee:

> The PPI was considered to be insufficient and it was noted that it could have been strengthened through prior consultation with focus groups to ensure that the research question was appropriate. The Committee also commented that the PPI could have been strengthened by the inclusion of a pregnant or recently pregnant representative.

The research team acknowledged the value of the reviewers' feedback and RDS staff learned an important lesson that funders scrutinise applications for appropriate PPI and will be influenced in their decisions by what they view as less than adequate involvement practices.

Discussion – hierarchy of knowledge versus new conceptualisation of relevant knowledges

As Bannister and O'Sullivan (2013) discuss elsewhere in this issue, what counts as valid knowledge is socially constructed. Applied health research in particular has depended upon and contributed to the paradigm of a hierarchy of evidence with randomised controlled trials being the gold standard for evidence of effective interventions (Williams & Glasby, 2010) and therefore those used to working with this model of clinical research can be disconcerted by policy expectations that they treat patients and carers as research partners (Ward et al., 2010; Williamson, 2007). We argue that involving patients and the public in applied health research is not a technical, scientific solution but a profoundly humanistic and social process that can involve messy emotions and working in unfamiliar ways (Barnes & Cotterell, 2011). Clinicians have historically had a powerful role in society but their expertise may not include advanced methodological skills (Gabbay, 2011). Their expertise is primarily mobilised within the clinic and may not extend to a knowledge of patients' lives. Historically there has been mistrust of researchers amongst some patient groups and longstanding debates continue about the democratic and emancipatory goals of user-led research (Purtell, Rickard, & Wyatt, 2012). Empowerment is a term connoting freedom from power and there have been examples of researchers abusing their power as in the case of the Alder Hay and Bristol enquiries in the UK (Williamson, 2010). However, any naive assumptions that clinical research is necessarily oppressive do not withstand empirical investigation (Epstein, 2007). Foucault taught us that power can be productive and so the challenge is how to balance power and responsibility and in this case of applied health research, how to integrate lay, clinical practice-based and academic knowledge.

Arnstein's well-known ladder of participation has been critiqued for its normative and linear assumptions (Tritter & McCallum, 2006) and we acknowledge that our case study examples are not user-led research; qualified researchers have assumed primary responsibility for research governance and for achieving study aims. However, in two of the cases researchers were willing to share some of their power with new partners. Our first case study presented an example of how patients misunderstood what they were being asked within a questionnaire that would have affected the validity of the statistical results had they not tested and re-designed the research instrument. Patients also discussed the relevance of the questionnaire items and as a result fatigue was added as an important outcome measure. In a reversal of the more usual roles in the clinic, the patients became knowledge producers as they made recommendations to the research team and to the clinical assessors. The second case study demonstrated a change of mind-set by a researcher used to working in the academy with quantitative research methods but willing to be challenged, to traverse beyond the academy into the community and cross over methodological boundaries. This radical shift from consultation to co-production entails giving voice to members of a group that might be described as 'hard to reach' or 'seldom heard' as co-interviewers. The instance of the failed funding application in case study three demonstrates that, however sophisticated the scientific methods, if the proposed intervention has not been discussed in sufficient detail with relevant patients, researchers miss out on the

insights of those who have first-hand experience or 'experiential expertise'. The male 'expert patient' could not have experienced gestational diabetes and arguably is less likely to have considered the need for childcare or the aesthetic implications of wearing the insulin pump or the additional discomfort of wearing a monitoring device so soon after childbirth. We cannot claim conclusively that this was the sole reason for the funding application being rejected but reviewers' comments indicate that it was a contributory factor in the panel's decision.

Brett et al. (2012) called for further conceptual clarification of PPI and we seek to contribute to such clarification. There is a tendency to 'nominalise' PPI so that what is actually a process is reified as a noun (Fairclough, 1992, p. 25). We suggest that current definitions of PPI conflate people with experiential knowledge (often service users, carers or patients) with members of the public and here we discuss what we see as separate roles within applied health research for these two identities. Our case studies indicate that the distinction is likely to be important both in theory and in practice. Clearly everyone, including academics and clinical researchers, is a member of the general public. An often-used rhetorical device to dismiss the views of patients is to dismiss them as 'unrepresentative' (Little et al., 2002). A simplistic retort is that clinicians and academics are also unrepresentative. We believe that sociological perspectives on representation may help the field of PPI to progress and so reduce the dissonance or mismatch between policy and practice (Renedo & Marston, 2011). In case study three, the diabetes charity was a stakeholder in the research and the male expert patient had a role to play in endorsing the need for the study but the particular and important perspectives of pregnant women or those with recent experience of childbirth were inadequately sought or represented. Whilst members of the public can play a role as lay members of funding panels and as lay reviewers and so on, in the case of applied health research, especially where potentially disruptive interventions are to be tested, it would seem most appropriate to involve people who are as similar as possible to those likely to be recruited into a study and also consider whether there are important differences between people that need to be included. Three different research roles for lay people: individual patients, patient group members and patient representatives or advocates are distinguished by Williamson (2007) and we suggest that the function of lay representation on a funding panel, while important, should be regarded as distinct from mobilising the experiential knowledge of patients, service users or carers to inform the design of applied health research. Case study one outlined how patients involved in an on-going Research User Group added value to health questionnaires and to the clinical research process. Case study two indicates that patient groups may be willing to collaborate as partners in research or knowledge mobilisation, especially where their views are respected, meetings take place on their terms and researchers are willing to negotiate and to design their research in a collaborative fashion. Case study three demonstrated the problems derived from consulting a patient group and an 'expert patient' but not individual patients with direct experience of the condition to be studied.

Conclusion

International health policies have recognised a variety of roles that patients, carers and the public can play in research. However, limited 'gold standard' evidence exists that would prove conclusively that PPI always results in more relevant, more acceptable or more ethical research. Nevertheless, emerging evidence suggests that this is *likely* to be the case (Brett et al., in press; Staley, 2009) and therefore we suggest that this, along with the moral imperatives for involving patients, carers and the public in research, should be regarded as 'good enough' evidence to inform research practice, especially when designing studies that involve sensitive topics or when participants are being asked to undergo interventions. We have provided examples of how first-hand experience of a health condition can be mobilised to offer valuable contributions to research. We have also shown how one research team made assumptions about their prospective research subjects that could

(and should) have been tested through dialogue with experts by experience. We also conclude that the term 'PPI' should be disaggregated to distinguish conceptually between lay people involved in scrutinising research and experts by experience who are a particular sub-set of the general public, in order to ensure appropriate involvement in different research processes.

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